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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,226	12/14/2006	Catharina Everdina Hissink	313632002300	2740

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EXAMINER	
JONES JR., ROBERT STOCKTON	
ART UNIT	PAPER NUMBER
1762	

NOTIFICATION DATE	DELIVERY MODE
09/26/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOfficeSD@mofo.com
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Office Action Summary	Application No.	Applicant(s)	
	10/586,226	HISSINK ET AL.	
	Examiner	Art Unit	
	ROBERT JONES JR.	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-23,25-27,30,31,36 and 39* is/are pending in the application.

5a) Of the above claim(s) *25-27,30,31,36 and 39* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-23* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/12/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 May 2011 has been entered.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-14 and 16-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Langer et al (US 6,160,084; cited in previous Office Action).

4. Regarding Claims 1 and 2, Langer teaches biodegradable shape memory polymer compositions which include at least one hard segment and at least one soft segment (Abstract).

5. The melting point or glass transition temperature of the hard segment is preferably between -30 and 270°C (col. 3, lines 10-11). The lower region of this range,

which includes temperatures from -30 to just below 37°C, describes hard segments which possess a melting point or glass transition temperature below human body conditions. According to Langer, melting point or glass transition temperature describe a change in state from a solid to liquid state (col. 3, lines 20-21). Thus, it is evident that within the aforementioned range, Langer contemplates hard segments which are liquid (i.e. completely amorphous) at human body conditions.

6. The melting point or glass transition temperature of the hard segment is at least 10°C higher than the melting point or glass transition temperature of the soft segment (col. 3, lines 7-10). This effectively describes a maximum range of melting point or glass transition temperature for the soft segment of between -40 and 260°C. Again, the lower region of this range, which includes temperatures from -40 to just below 37°C, describes soft segments which possess a melting point or glass transition temperature below human body conditions. Thus, Langer also contemplates soft segments which are liquid (i.e. completely amorphous) at human body conditions.

7. It is true that Langer also contemplates hard and soft segments which are not amorphous at human body conditions. These embodiments are represented by segments falling within the range of suitable transition temperatures above 37°C. Nevertheless, selection of hard and soft segments which are amorphous under human body conditions is equivalent to selecting segments having a glass transition or melting point within a range which overlaps a claimed range (in this case, the unstated range would be "completely amorphous at 37°C", or "having a glass transition temperature or melting point below 37°C"). As set forth in MPEP 2144.05, in the case where the

claimed range "overlap or lie inside ranges disclosed by the prior art", a *prima facie* case of obviousness exists, In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

8. Thus, it would have been obvious to one of ordinary skill in the art to select hard and soft segments which are liquid (i.e. completely amorphous) at 37°C (i.e. human body conditions) when forming Langer's polymers. Langer's hard and soft segments are selected from a variety of polymers (col. 3, lines 26-33); thus, said segments read on the claimed pre-polymers A and B.

9. Exemplary embodiments illustrate linking hard and soft segments through trimethylhexane-1,6-diisocyanate chain extenders (col. 14, lines 44-53). It would have been obvious to one of ordinary skill in the art at the time of the invention to employ this linking technique when combining other hard and soft segments, as it has demonstrated success in forming the desired type of copolymer.

10. Langer as applied above reads on all elements of Claims 1, 2, 22, and 23.

11. Regarding Claims 3 and 4, Langer contemplates hard and/or soft segments formed from polymers such as polyhydroxyacids and polyalkanoates (containing ester linkages); polyanhydrides (containing anhydride linkages); polymers containing carbonate linkages; and polyetheresters (containing ester linkages and polyether segments) (col. 3, lines 26-34).

12. Regarding Claim 5, Langer teaches polyalkylene glycols as suitable polymer blocks (col. 6, line 67). A variety of other suitable polymer blocks are disclosed throughout Langer (see, e.g., col. 6, line 46 - col. 7, line 30). These polymers are

described as being equally suitable, and are therefore considered to be equivalents. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a polyalkylene glycol along with any other of these suitable polymers as an additional segment. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

13. Regarding Claim 6, Langer teaches polymers formed from hydroxycarboxylic acids (col. 6, lines 51-53; col. 7, lines 26-28; col. 7, lines 37-38).

14. Regarding Claims 7-9 and 12, Langer's examples illustrate a method for forming prepolymers from cyclic monomers (L,L-lactide and glycolide) by initiating ring-opening polymerization with ethylene glycol (a non-cyclic initiator) (col. 14, lines 15-22). It would have been obvious to one of ordinary skill in the art at the time of the invention to employ this technique when forming segments having a glass transition or melting point falling within the range discussed above, as it has demonstrated success in forming the desired product.

15. Regarding Claim 10, other suitable polymer segments include poly[glycolide-co-(ε-caprolactone)] (col. 7, line 28). A preferred weight ratio of the monomers is not disclosed. However, when faced with a combination of equivalent elements (in this case, the comonomers glycolide and caprolactone), one of ordinary skill in the art would be motivated by common sense to select a 1:1 ratio absent evidence of unexpected

results. Case law holds that "[h]aving established that this knowledge was in the art, the examiner could then properly rely…on a conclusion of obviousness, 'from common knowledge and common sense of the person of ordinary skill in the art within any specific hint or suggestion in a particular reference." *In re Bozek*, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

16. Regarding Claim 11, other suitable polymer segments include poly(lactide-co-glycolide) (col. 7, lines 37-38). A preferred weight ratio of the monomers is not disclosed. However, when faced with a combination of equivalent elements (in this case, the comonomers lactide and glycolide), one of ordinary skill in the art would be motivated by common sense to select a 1:1 ratio absent evidence of unexpected results. Case law holds that "[h]aving established that this knowledge was in the art, the examiner could then properly rely…on a conclusion of obviousness, 'from common knowledge and common sense of the person of ordinary skill in the art within any specific hint or suggestion in a particular reference." *In re Bozek*, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

17. Regarding Claims 13 and 14, suitable soft segments include PEG (col. 8, line 1) as well as poly(ethylene oxide-co-propylene oxide) (PEO-co-PPO; equivalent to PEG-co-PPG) (col. 8, lines 23-24).

18. Regarding Claim 16, the preferred number average molecular weight of polymer blocks (i.e. prepolymers) is between 500 and 15,000 (col. 6, lines 4-6).

19. Regarding Claim 17, suitable polymer segments include those which comprise caprolactone and glycolide (such as poly[glycolide-co-(ε-caprolactone)]; (col. 7, line

28)). Additionally, Langer's examples illustrate that p-dioxanone may be employed to form suitable prepolymer segments (col. 13, lines 61-63).

20. Regarding Claim 18, Langer at several points discloses polylactide (col. 7, line 3; col. 7, line 24) as being suitable for forming polymeric segments. Langer also teaches several copolymers which comprise lactide (col. 7, lines 27 and 37-38). Langer is silent with respect to which lactide isomer(s) would be suitable in forming said polymers and copolymers. However, it is well known in the art that lactide exists in only three forms: L,L-lactide; D,D-lactide; and D,L-lactide. In this instance, the genus "lactide" is sufficiently small that one of ordinary skill in the art would at once envisage the use of each member, including the use of the species D,L-lactide. It has been held that a prior art genus containing only 20 compounds and a limited number of variations in the generic chemical formula inherently anticipated a claimed species within the genus because "one skilled in [the] art would... envisage *each member"* of the genus. *In re Petering*, 301 F.2d 676, 681, 133 USPQ 275, 280 (CCPA 1962) (emphasis in original).

21. Regarding Claim 19, the preferred number average molecular weight of polymer blocks (i.e. prepolymers) is between 500 and 15,000 (col. 6, lines 4-6).

22. Regarding Claim 20, Langer's general disclosure does not state a preferred range in which to include segments equivalent to the claimed pre-polymer B. However, one of ordinary skill in the art would be motivated to look to Langer's examples for guidance, as these represent successful embodiments of Langer's composition. Table 3 (col. 15) illustrates that segments formed from polycaprolactone or poly(lactide-co-glycolide) may be incorporated in amounts ranging from 46.2 to 64.5 wt%.

23. Regarding Claim 21, Langer is silent with respect to intrinsic viscosity. However, Langer contemplates the formation of copolymers which are identical to the claimed copolymers. The courts have held that "a compound and all its properties are mutually inseparable", *In re Papesch*, 315F.2d 381, 137 USPQ 42, 51 (CCPA 1963). Further, attention is drawn to MPEP 2112.01, which states that "products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.", *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). As such, Langer's copolymers will intrinsically possess an intrinsic viscosity which falls within the claimed range.

24. Claims 4 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langer as applied to claim 1 above, and further in view of Rashkov et al (Macromolecules, 1996, p. 50-56; cited in previous Office Action).

25. Regarding Claims 4 and 13-15, Langer remains as applied to Claim 1 above. Langer teaches that both polyethylene glycol (PEG) (col. 8, line 1) and polylactide (col. 7, line 24) are suitable polymer segments. Langer does not teach a copolymer wherein PEG is an initiator for ring-opening polymerization.

26. In the same field of endeavor, Rashkov teaches that PLA/PEG copolymers are of great interest as macromonomers for preparation of new macromolecular materials. Copolymerization offers the possibility of varying hydrophilic/hydrophobic and soft/hard

segment ratios and, thus, constitutes a very attractive means to modulate the basic properties of each homopolymer (p. 50, Introduction, para. 1). Said PLA/PEG copolymers are synthesized by introducing PEG having a molecular weight of 600, 1000, or 2000 (p. 50, Materials) to a flask, followed by introduction of lactide (a cyclic monomer) and a catalyst (p. 50-51, Methods). The result is a copolymeric macromonomer formed by using PEG having a molecular weight of 600, 1000, or 2000 as an initiator for ring-opening polymerization of L-lactide.

27. It would have been obvious to one of ordinary skill in the art to employ Rashkov's PEG/PLA copolymers as segments in Langer's multiblock copolymers for the benefit of modulating the physical properties of the individual segments and because they are directly taught as being suitable for use as macromonomers for preparation of macromolecular materials. Modification of Langer in view of Rashkov reads on Claims 4 and 13-15.

Response to Arguments

28. Applicant's arguments, see particularly paragraphs 1-5 of the section entitled "The Rejection for Anticipation" and the discussion found in the Declaration by Dr. Flipsen, filed 12 April 2011, with respect to the rejection of claims 1-3, 6-9, 12, 16, 17, and 19-23 under 35 USC 102(b) have been fully considered and are persuasive. Specifically, upon further consideration, it appears that the exemplary copolymers disclosed by Langer and applied in the previous rejection are not completely amorphous

at human body conditions. Thus, the Applicant's arguments coupled with the amendment to Claim 1 are sufficient to overcome the previous rejection. However, upon further consideration, a new grounds of rejection is made in view of Langer as set forth above.

29. The Applicant's response to arguments regarding paragraphs 32-47 and 50-55 of the previous office action are moot in view of the new grounds of rejection based on Langer presented above.

30. The Applicant's remarks regarding paragraphs 48-49 of the previous office remain pertinent to the new grounds of rejection, inasmuch as the rejection remains based on the teachings of Langer et al. The Applicant argues that to the extent that Langer's materials have shape memory when used within the human body, it cannot be the case that low transition temperatures of the hard segment are possible. The Applicant maintains that crystallinity must be retained in order to achieve the shape memory property.

31. Langer envisions the aforementioned shape memory polymers for a wide variety of applications including those outside the human body. For example, in biomedical applications, Langer contemplates the use of orthopedic braces and tape for preparing casts (col. 12, lines 15-16). Non-medical applications are also contemplated, such as disposable diapers and packaging materials (col. 12, lines 52-57). Articles such as car bumpers are also contemplated (col. 13, lines 13-18). Thus, applications exist in which Langer's shape memory polymers would be functional or even desirable with hard segments having a transition temperature below human body temperature.

32. Absent any further argument or amendment, the claims stand rejected under 35 USC 103(a) as set forth above.

Conclusion

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT JONES JR. whose telephone number is (571)270-7733. The examiner can normally be reached on Monday - Thursday, 9 AM - 5 PM.

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

35. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RSJ

/DAVID W WU/
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